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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/583,179

08/25/2008

Heng Hang Tsai

490352-3004/US

2216

34205

7590

12/15/2010

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EXAMINER

BASS, DIRK R

ART UNIT

PAPER NUMBER

1777

MAIL DATE

DELIVERY MODE

12/15/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/583,179	TSAI ET AL.	
	Examiner	Art Unit	
	DIRK BASS	1777	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 November 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 and 32-47 is/are pending in the application.
- 4a) Of the above claim(s) 5,9-12,18,19 and 45-47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-8,13-17,20-26 and 32-44 is/are rejected.
- 7) ☒ Claim(s) 37-38, 40, 42 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/23/07, 10/3/07, 1/4/08, 9/1/10, 10/21/10</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's response filed November 5, 2010 is acknowledged. Claims 5, 9-12, 18-19, and 45-46 are withdrawn from consideration for being drawn to a non-elected invention or species. Claims 1-4, 6-8, 13-17, 20-26, and 32-44 are pending and considered on the merits.

Election/Restrictions

Applicant's election with traverse of group I, claims 1-26 and 32-34, in the reply filed on November 5, 2010 is acknowledged. The traversal is on the ground(s) that Nam et al does not disclose the common linking feature of groups I and II. This is not found persuasive because Nam et al., (Protein Expression and Purification, vol. 24, pgs. 282-291, IDS) explicitly discloses a protein bound to a substrate, as required in the device and method. The examiner reminds applicant that while Nam discloses binding the chaperone proteins to a substrate in order to separate said proteins, Nam still discloses chaperone proteins bound to a substrate, thereby anticipating applicant's common linking feature and establishing a lack of unity between groups I and II.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. **Claims 25-26 and 41** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claims 25-26 recite the limitation "the biological sample". There is insufficient antecedent basis for this limitation in the claim.

5. Claim 41 recites the limitation "the substitutions". There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. **Claims 1-4, 15-17, 20-22, 25-26, 32, 36, and 43** are rejected under 35 U.S.C. 102(b) as being anticipated by Fersht, USPA 2002/0142369 (Fersht).
8. Regarding claims 1-4, and 32, Fersht discloses a protein separation device comprising a chaperone protein, specifically GroEL, immobilized on a substrate (abstract, ¶ 0007-0008, Claims 1-7).
9. Regarding claims 15-17, Fersht discloses that the chaperone is obtainable from a bacteria source such as *Escherichia coli* (Claim 7).
10. Regarding claims 20-22, Fersht discloses that the substrate is a bead or array made from a plastics material (¶ 0060, 0080).
11. Regarding claims 25-26, the limitations specifying the “biological sample” are deemed to be statements with regard to the intended use and are not further limiting in so far as the structure of the product is concerned. In article claims, a claimed intended use must result in a **structural difference** between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. MPEP § 2111.02.
12. Regarding claims 36 and 43, Fersht discloses that the specificity of GroEL is directed to a particular protein (Claims 1-6).
13. **Claims 1-4, 13-17, 20, 22-26, 32-36, 39, and 43-44** are rejected under 35 U.S.C. 102(b) as being anticipated by Taguchi et al., Nature Biotechnology, vol. 19 (Sept. 2001) (Taguchi, IDS).
14. Regarding claims 1-4, 13-14, 32, 36, and 43, Taguchi discloses a protein separation device comprising GroEL/GroES complex bound to a substrate (abstract, pg. 861 Results section, fig. 1).
15. Regarding claims 15-17, Taguchi discloses that the chaperone is obtainable from *Escherichia coli* (pg. 861, Introduction).
16. Regarding claims 20 and 22-24, Taguchi discloses that the substrate is an array type having a surface modified with streptavidin (fig. 1).
17. Regarding claims 25-26, the limitations specifying the “biological sample” are deemed to be statements with regard to the intended use and are not further limiting in

so far as the structure of the product is concerned. In article claims, a claimed intended use must result in a **structural difference** between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. MPEP § 2111.02.

18. Regarding claims 33-35, Taguchi discloses GroEL is engineered to have cysteine at residue 490, which binds to biotin to form a biotin-cysteine conjugate, said biotin-cysteine conjugate being reactable with streptavidin located on the surface of a substrate (pg. 861, Results section ¶ 0002, fig. 1).

19. Regarding claims 39 and 44, Taguchi discloses a protein separation device comprising GroEL in an optimized orientation to bind a target protein wherein the specificity of GroEL is modified to a specificity of another chaperone protein (abstract).

Claim Rejections - 35 USC § 103

20. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

21. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

22. **Claims 6-8** are rejected under 35 U.S.C. 103(a) as being unpatentable over Fersht.

23. Regarding claim 6, Fersht discloses using an hsp60 molecular chaperonin but does not specifically disclose said chaperonin comprising a double ring configuration where one ring is heptameric and the other ring is dimeric, trimeric, tetrameric,

Art Unit: 1777

pentameric, or hexameric. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to include such a configuration for hsp60, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice (MPEP 2144.07).

24. Regarding claims 7-8, Fersht discloses using CCT as a chaperone for protein binding (§ 0017) but does not disclose binding another chaperone protein such as rubisco or CCT to said GroEL. At the time of invention, it would have been an obvious matter of design choice to bind CCT to GroEL in the protein separation device, since applicant has not disclosed that doing so solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well with the configuration disclosed by Fersht.

Allowable Subject Matter

25. **Claims 37-38, 40, and 42** are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIRK BASS whose telephone number is (571) 270-7370. The examiner can normally be reached on Mon - Fri (9am-4pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vickie Kim can be reached on (571) 272-0579. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1777

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/DRB/

Dirk R. Bass

/Vickie Kim/

Supervisory Patent Examiner, Art Unit 1777